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Novel Method of Fabricating Individual Trays for Maxillectomy Patients by Computer-Aided Design and Rapid Prototyping

Zhi Huang, DDS, Xin-zhi Wang, DDS, PhD, & Yue-zhong Hou, BDS

Department of Prosthodontics, Peking University School and Hospital of Stomatology, Beijing, China

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Keywords
Clinical application; feasibility; impression technique; maxillofacial prosthesis.

Correspondence
Xin-zhi Wang, Department of Prosthodontics, Peking University School and Hospital of Stomatology, No. 22 Zhongguancun Nan Dajie, Haidian District, Beijing 100081, China.
E-mail: xinzwang@sina.com.cn

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Abstract

Purpose: Making impressions for maxillectomy patients is an essential but difficult task. This study developed a novel method to fabricate individual trays by computer-aided design (CAD) and rapid prototyping (RP) to simplify the process and enhance patient safety.
Materials and Methods: Five unilateral maxillectomy patients were recruited for this study. For each patient, a computed tomography (CT) scan was taken. Based on the 3D surface reconstruction of the target area, an individual tray was manufactured by CAD/RP. With a conventional custom tray as control, two final impressions were made using the different types of tray for each patient. The trays were sectioned, and in each section the thickness of the material was measured at six evenly distributed points. Descriptive statistics and paired *t*-test were used to examine the difference of the impression thickness. SAS 9.3 was applied in the statistical analysis. Afterwards, all casts were then optically 3D scanned and compared digitally to evaluate the feasibility of this method.
Results: Impressions of all five maxillectomy patients were successfully made with individual trays fabricated by CAD/RP and traditional trays. The descriptive statistics of impression thickness measurement showed slightly more uneven results in the traditional trays, but no statistical significance was shown. A 3D digital comparison showed acceptable discrepancies within 1 mm in the majority of cast areas. The largest difference of 3 mm was observed in the buccal wall of the defective areas. Moderate deviations of 1 to 2 mm were detected in the buccal and labial vestibular groove areas.
Conclusions: This study confirmed the feasibility of a novel method of fabricating individual trays by CAD/RP. Impressions made by individual trays manufactured using CAD/RP had a uniform thickness, with an acceptable level of accuracy compared to those made through conventional processes.

Individual trays are regarded as the best means by which to guarantee accuracy in impressions in prosthodontics.[1] In fixed prosthodontics, variations between casts of stock and individual trays are generally deemed to be small and, therefore, are assumed to have little substantive bearing on clinical outcomes.[2] However, an in vitro study has suggested that unequal distribution of the impression material in stock trays can result in dimensional changes in the cast.[3] By contrast, individual trays can provide a uniform thickness in the impression material, minimizing cast distortion. Being designed to fit with the majority of oral cavity morphologies across the normal population means stock trays have the advantage of convenience in most cases, but they appear to be inadequate for use in maxillofacial prosthetics, where accuracy is of greater concern.

In maxillofacial prosthetics, impression taking is more complicated. The traditional method involves the making of a preliminary impression, fabrication of an acrylic individual tray, and a final impression-making stage.[4] Oh and Roumanas reported an alternate technique to fabricate a customized impression tray by duplicating an interim obturator prosthesis.[5] However, making an individual tray from a diagnostic cast requires a relatively accurate preliminary impression, which can be difficult to obtain and in some cases entails multiple attempts. Furthermore, after total or partial resection of the maxilla, patients can develop an oral–nasal fistula, which increases the risk of impression material being aspirated. For many years, prosthodontists have struggled to acquire the necessary level of accuracy and safety in making impressions for these patients.[5,6]

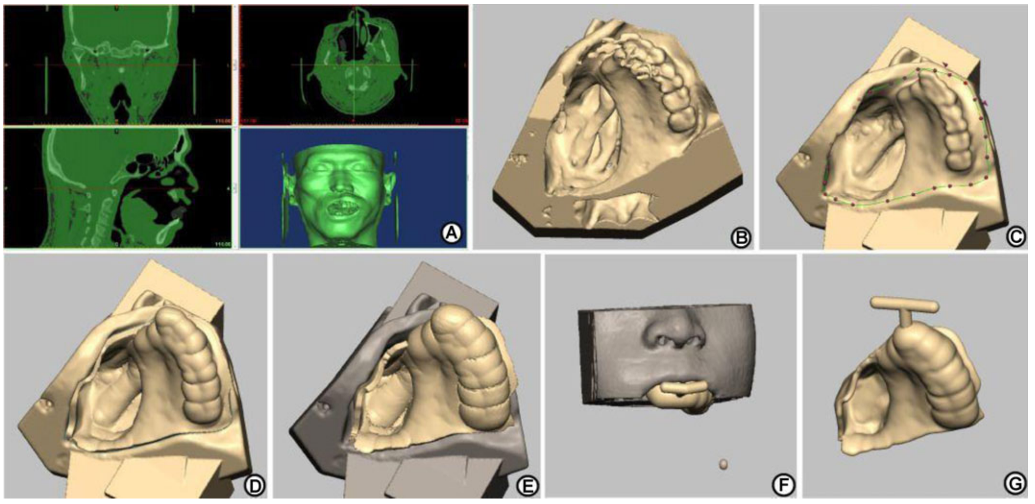

Figure 1 (A) 3D reconstruction of the selected value range from the DICOM data; (B) digital diagnostic cast imported by the FREEFORM Clay tools from which the individual impression tray was designed; (C) images after shadows were trimmed off, undercuts (especially in the maxillectomy defect area) were blocked out, and the border of the tray was selected using a curve drawing tool; (D) the selected area was embossed to 3 mm to leave space for impression material; (E) the selected area was embossed a further 3 mm to form the body of the tray, from which the former embossed cast was subtracted; (F) the position of the patient's lip can be seen, and a holding grip was designed to avoid contact with the soft tissue; (G) after surface smoothing, computer-aided design of the individual tray was complete.

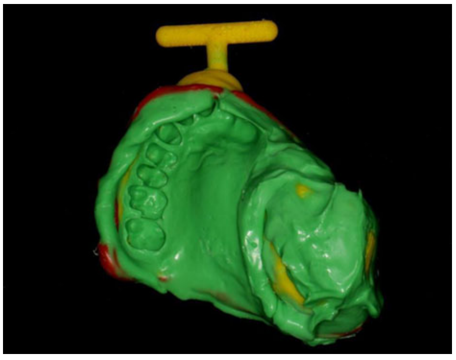

Figure 2 On the second patient visit, a final impression was taken for the CAD/RP individual trays.

Digital acquisition and digital impressions are making headway in fixed prosthodontics. Clinicians have started to use digitized impression-acquiring techniques to make impressions for crowns and fixed partial dentures. The manufacturing of ocular, auricular, and facial prostheses based on computer-aided design and computer-aided manufacturing (CAD/CAM) or rapid prototyping (RP) has also been reported.[7–9] Optical scanning techniques used in data acquisition are convenient, accurate, and safe, avoiding human error and the use of impression materials; however, for an intraoral removable prosthesis, a static image devoid of border molding does not include the necessary information on frenum and muscle movements, leading to difficulties in determining the outline of the denture border.

Currently, clinicians must rely on individual trays to obtain a suitably accurate final impression for maxillectomy patients. The aim of this study was to demonstrate a novel computer-aided method to help prosthodontists fabricate individual trays without subjecting their patients to the risks involved in taking diagnostic casts, while providing sufficiently accurate contours for the individual trays. The hypothesis was that the CAD/RP individual trays fulfill the competence of traditional individual trays clinically.

Materials and methods

Five unilateral maxillectomy patients who had undergone tumor resection surgery at least 3 months prior to the study were recruited. All patients showed satisfactory healing at the surgical site with no recurrence and no further surgical treatments planned. According to Aramany's Classification, three patients were Class I, and two were Class II. Informed consent was obtained in writing for each patient. This study and the

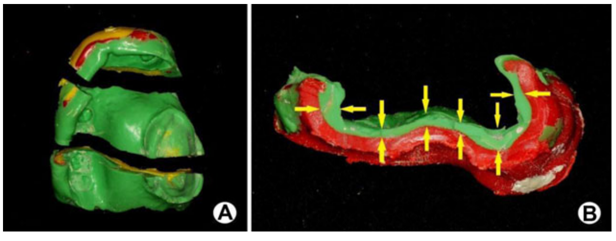

Figure 3 (A) The trays were sectioned at predetermined sectioning lines running horizontally thorough the impression tray. The sectioning was done with a handpiece with separating disc; (B) measurements of impression material thickness were made with a slide gauge to an accuracy of 0.02 mm at six evenly distributed points.

Table 1 Basic statistical measures of impression material thickness on CAD/RP individual trays (test group) and traditional trays (control group)

	N	Mean (mm)	Std deviation	Kurtosis	Range (mm)
Test group	60	4.07	1.58	3.9	7.52
Control group	60	4.5	1.8	0.63	8.38

Table 2 Estimated quantile of impression material thickness on CAD/RP individual trays (test group) and traditional trays (control group)

Quantile	Control group (mm)	Test group (mm)
100% Max	9.46	9.1
99%	9.46	9.1
95%	8.14	8.64
90%	7.07	6.27
75% Q3	5.41	4.17
50% Median	4.26	3.67
25% Q1	3.42	3.36
10%	2.34	2.95
5%	1.46	2.09
1%	1.08	1.58
0% Min	1.08	1.58

Table 3 Paired *t*-test results of the mean thickness value of the CAD/RP individual trays (test group) and traditional trays (control group)

DF	*t* Value	Pr > ltl
59	−1.97	0.0537

documents pertaining to informed consent were approved by the ethics committee of Peking University School of Stomatology, approval No: PKUSSIRB-2012025.

During the first patient visit, GE Lightspeed VCT xTE (GE Healthcare, Chalfont St. Giles, UK) was used to acquire a computed tomography (CT) scan of the patient including the target area to be modeled (from the Frankfort plane to the mandibular plane). During the scanning process, cotton rolls were placed in the maxillary buccal and labial vestibule to prevent the buccal and labial soft tissues from coming into contact with the adjacent teeth or alveolar ridges. Baseplate wax was shaped and set between the upper and lower dentition to separate them and form adequate buccal and labial fullness on the defective side. Following this, Digital Imaging and Communications in Medicine (DICOM) data were exported and processed by MIMICS 10.0 (Materialise, Leuven, Belgium). Figure 1 shows the CAD model of the individual tray. DICOM images were then segmented. The threshold was set at −700 to 2850 predefined for soft tissue and enamel by the software. A three-dimensional (3D) reconstruction of the selected value range was carried out (Fig 1A). Following this, the 3D model was trimmed using the cranio-maxillofacial (CMF)/simulation tool, leaving only the impression-taking area (Fig 1B). The digital diagnostic cast was then imported into the FREEFORM Clay tools (Geomagic, Morrisville, NC) from which the individual impression tray was designed using the following steps. First, the digital cast was prepared for the tray design. Shadows were trimmed off, and undercuts and unwanted areas were blocked out. The border of the tray was then selected using a curve drawing tool (Fig 1C), with the selected area embossed by 3 mm to leave space for the impression material (Fig 1D). The selected area was embossed a further 3 mm to form the body of the tray, from which the former embossed cast was subtracted (Fig 1E). The body of the individual tray was then formed. The position of the patient's lip could be seen, and a holding grip for the tray was designed to avoid contact with the soft tissue (Fig 1F). The final step was to smooth the surface to ensure the tray could be easily placed into the patient's mouth (Fig 1G).

Various CAM methods have been developed over the past few years. 3D printing was chosen for this study based on the cost and the need for less detail in the individual trays compared to the definitive prosthesis. The stereolithography (stl) file of the tray design was sent to a manufacturing company (Weisteck, Shenzhen, China) for the 3D printing (with an accuracy of 0.2 mm).

A conventional individual tray was also prepared for each patient. Rapid (Coltène, Alstatten, Switzerland) silicone elastomer material and a stock tray were used to take an impression. A diagnostic cast was poured. After the cast was set, undercut areas were blocked out with melted baseplate wax (Zhong Bei Yi Zhao Company, Beijing, China). Soft baseplate wax of double thickness was used as spacer. Preci-Tray (Yeti Dental, Engen, Germany) material was used to make the individual tray.

On the second patient visit, final impressions were taken with both traditional and CAD/RP individual trays (Fig 2). The impression material used was Variotime Light Flow (Heraeus Kulzer, Hanau, Germany). The cast was prepared with Die Stone (Heraeus Kulzer).

The feasibility of the novel fabrication method of individual trays was evaluated in two ways. The first was to see if the tray provided a uniform thickness of the impression material. Bomberg et al measured the thickness of the impression material beneath individual trays by sectioning the tray.[10] Other studies have used 3D analysis to determine the difference between casts; employing this method allowed us to compare the casts from conventional individual trays and CAD/RP trays directly.[11–13]

To measure the thickness of the impression material, all trays and impressions were analyzed immediately after removal of the Die Stone casts. The trays were sectioned at two predetermined sectioning lines set horizontally through the impression tray. The sectioning was carried out with a handpiece with separating disc (Drendel + Zweiling, Kalletal Germany) (Fig 3A). In each sectioned specimen, measurements of impression material thickness were made with a slide gauge (Endura, Shanghai, China) with an accuracy of 0.02 mm at six evenly distributed points (Fig 3B). The values of material thickness were divided into two groups: control group (traditional method) and test group (CAD/RP method). Descriptive statistics were used to examine the dispersion degree difference of the impression material thickness from the two methods, and paired *t*-test was used to examine the difference. SAS 9.3 was applied in the statistical analysis.

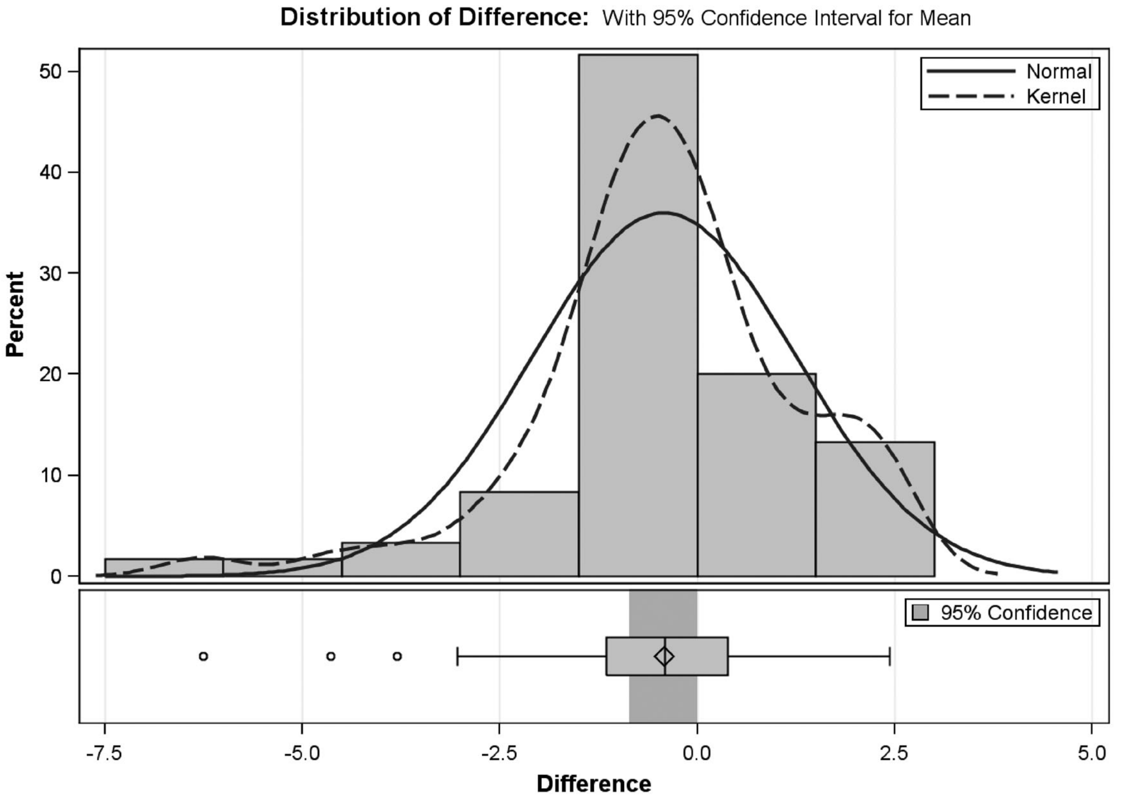

Figure 4 The paired *t*-test results of the mean impression thickness of the two groups.

Following this, 3D analysis was used to investigate the difference between the casts from conventional individual trays and CAD/RP trays directly.[11–13] The stone casts were optically scanned with an Activity 800 optical 3D scanner (Smartoptics, Bochum, Germany) after being left to set for at least 24 hours. The 3D images of the casts made from the two procedures for each patient were analyzed by Geomagic Qualify 12 (Geomagic). Geomagic aligned the two casts automatically, minimizing the risk of error that might arise from manual alignment. A 3D comparison was performed, in which any deviation between the two types of casts was quantified.

Results

Impressions of all five maxillectomy patients were successfully fabricated in the novel CAD/RP individual trays. When fitting the trays in the patients, little adjustment was needed, effectively reducing chairside working time.

In the descriptive statistics of impression thicknesses, the standard deviation and range of the control group were larger than those of the test group (Table 1), showing more discrete thickness values in the control group. The Kurtosis value and Quantile (Tables 1 and 2) showed that the test group distribution was more concentrated. The specimens of both the test and control group had a normal distribution, and paired *t*-test results showed the difference between the two groups cannot be accepted under 5% confidence level (Table 3, Fig 4).

The results of the 3D comparison are shown in Figure 5. The level of discrepancy between the two casts from the same patient is shown in different colors. In the majority of cast areas, discrepancies fell within the range of 0 to 1 mm as shown in green and yellow. The greatest difference was observed in the buccal wall of the maxillectomy defect areas, of up to 3 mm. Moderate deviations of about 1 to 2 mm were observed in the buccal and labial vestibular groove areas.

Discussion

As the presence of an oral–nasal fistula can increase the risk of a patient aspirating impression material, which can lead to serious problems,[14,15] the impression-making process poses a risk to maxillectomy patients and their prosthodontists. The method developed in this study enabled us to prepare individual trays for patients undergoing a maxillectomy in a digital manner, effectively reducing the number of times a patient would have to endure invasive processes in the development of an impression.

In vitro studies are widely used to assess the accuracy of impressions.[16] However, the primary aim of this study was to demonstrate the clinical application of a digitized method to fabricate individual trays for maxillectomy patients and to prove its viability, rather than to investigate the accuracy of impressions prepared using different kinds of trays. Nevertheless, measurement of impression material thickness and a 3D comparison of the cast contour between CAD and conventional

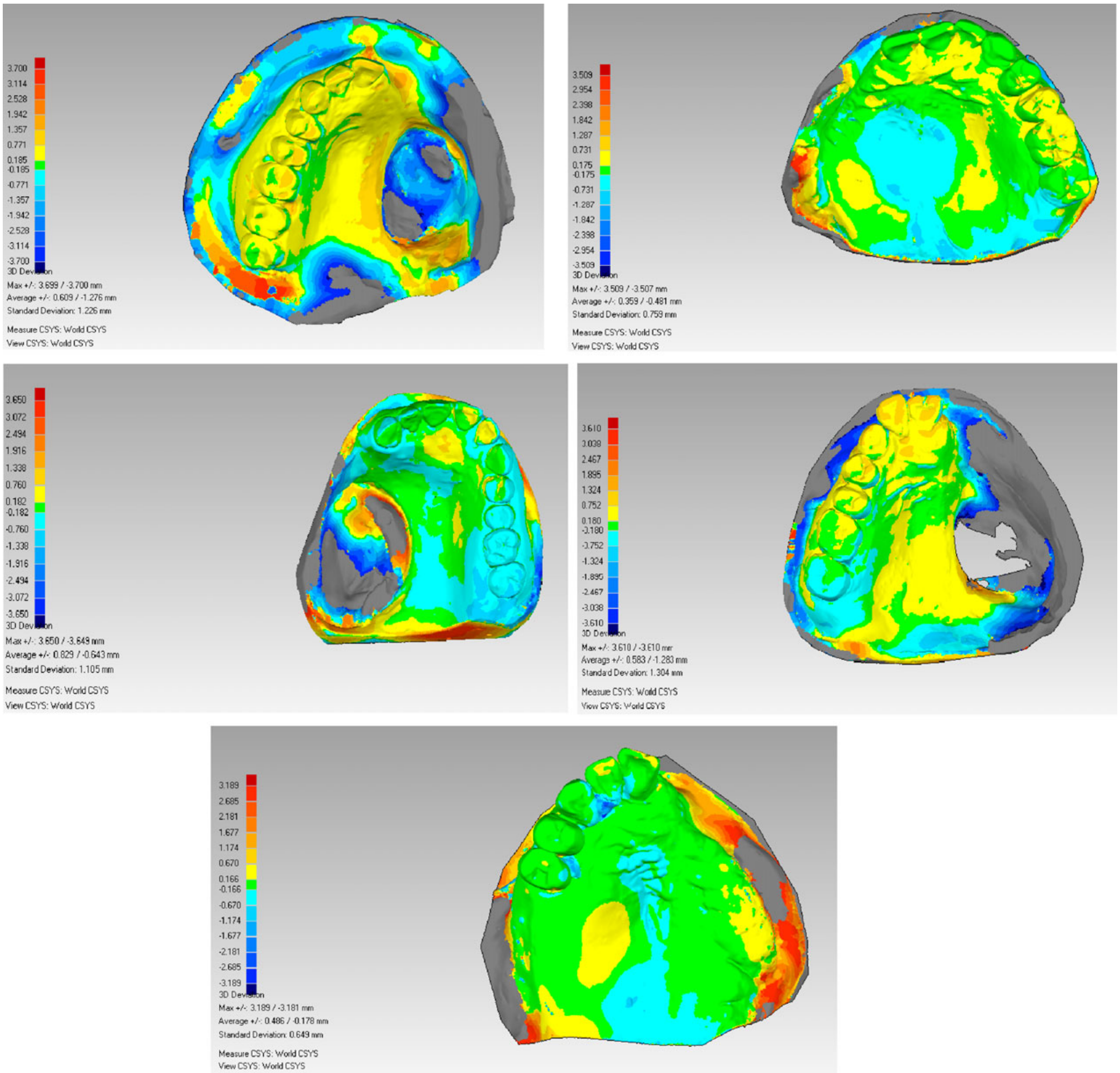

Figure 5 3D comparison of the two different casts from five patients.

casts showed the new method to be effective in producing trays to a sufficient degree of accuracy for clinical use.

It is widely accepted that elastomeric impression materials used in fixed prosthodontics offer the best stability with an even thickness of 2 to 4 mm, with the minimum dimensional changes likely to occur when the impression material is uniformly thin.[17] The total mean material thickness of 4.07 ± 1.58 mm from CAD/RP custom trays in our study showed the material thickness to be relatively stable compared to results from a previous study by Bomberg et al (standard deviation 1.11 to 2.43 mm).[10] When compared to conventional custom trays in our study, CAD/RP trays resulted in a more even impression material thickness, but with no statistical significance. The material thickness in the tray is affected by the way in which the tray is made as well as by the manner in which it is used. Problems such as incomplete seating, overcomplete seating, eccentric orientation, and centering of the tray can all cause unconformity of the material. Further studies evaluating a greater number of specimens should help to confirm the validity and usefulness of this method of fabrication.

The 3D comparison in this study showed the CAD/RP tray casts to be made to an acceptable standard. The casts from these CAD/RP individual trays would be of sufficient quality to be usable in removable dentures. In most denture-bearing areas, including teeth, palatal areas, and the border of a defect, deviation between the two types of casts was less than 1 mm. The biggest difference was measured on the buccal wall of the defective side; this may be the result of disparity in the buccal fullness during the CT scan for CAD/RP individual trays and the taking of diagnostic impressions for conventional trays. Further variance was observed in the morphology of the vestibular groove. The border of individual trays is typically determined during the fitting of a tray in the patient's mouth. Trimming of any overextension and border molding may result in slight differences in the border morphology. Also, shifting of the tray position when taking the final impression may lead to overextension or inadequate extension in the border area.

Finally, the cost of the digitized individual tray must be taken into consideration. This includes the cost of a CT scan and the manufacturing process. In the future, it should be possible to use the existing CT data from a patient's postsurgery scan; thus, the only additional cost to the patient would be US$30 as a 3D printing fee, which would be acceptable to most patients given the benefits of a less-invasive medical procedure.

Long-term clinical trials should ultimately be conducted on CAD/RP individual trays, to establish the benefits and practicality of their use clinically. The CAD/RP fabrication method outlined here has the potential to be applied to other areas of surgery and dentistry (e.g., implant individual trays, surgical template for oral implants).

Conclusion

The novel method of fabricating individual trays by CAD and RP outlined here offers clinical benefits to maxillofacial patients and prosthodontists.

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